

BEFORE THE DEPARTMENT OF PUBLIC
HEALTH AND HUMAN SERVICES OF THE
STATE OF MONTANA

In the matter of the adoption of New)	NOTICE OF PUBLIC
Rules I through XXX and the repeal of)	HEARING ON PROPOSED
ARM 37.112.101, 37.112.105,)	ADOPTION AND
37.112.106, 37.112.107, 37.112.112,)	REPEAL
37.112.113, 37.112.114, 37.112.120,)	
37.112.122, 37.112.124, 37.112.126,)	
37.112.128, 37.112.130, 37.112.135,)	
37.112.136, 37.112.140, 37.112.143,)	
and 37.112.146 pertaining to tattooing)	
and body piercing)	

TO: All Interested Persons

1. On October 25, 2006, at 1:30 p.m., a public hearing will be held in the auditorium of the Department of Public Health and Human Services Building, 111 N. Sanders, Helena, Montana to consider the proposed adoption and repeal of the above-stated rules.

The Department of Public Health and Human Services will make reasonable accommodations for persons with disabilities who need an alternative accessible format of this notice or provide reasonable accommodations at the public hearing site. If you need to request an accommodation, contact the department no later than 5:00 p.m. on October 18, 2006, to advise us of the nature of the accommodation that you need. Please contact Dawn Sliva, Office of Legal Affairs, Department of Public Health and Human Services, P.O. Box 4210, Helena, MT 59604-4210; telephone (406)444-5622; FAX (406)444-1970; e-mail dphhslegal@mt.gov.

2. The rules as proposed to be adopted provide as follows:

RULE I PURPOSE (1) The rules in this chapter pertain to tattooing and body piercing establishments under Title 50, Chapter 48, MCA, that are licensed by the Montana Department of Public Health and Human Services. Unless otherwise specified by the rules of the local health authority, the rules in this chapter do not apply to tattooing and body piercing establishments that are licensed solely by local boards of health pursuant to 50-48-203, MCA.

AUTH: 50-48-103, MCA

IMP: 50-48-103, 50-48-203, MCA

RULE II DEFINITIONS (1) "Aftercare instructions" means verbal and written instructions that the client should follow to prevent infection and promote healing of the skin after receiving a tattoo or body piercing.

(2) "Antiseptic" means a substance applied to the skin that kills or inhibits the

growth of disease-causing microorganisms.

(3) "Artist" means a tattooist or body piercer.

(4) "Aseptic technique" means a procedure that prevents contamination of any object or person.

(5) "Body piercer" means a person who engages in the practice of piercing as defined in 50-48-102, MCA.

(6) "Body piercing establishment" means any room, space, shop, or salon, including a temporary or mobile facility, where body piercing is practiced.

(7) "Client" means the person whose skin will be tattooed or pierced.

(8) "Contaminated" means the probable presence of disease-causing microorganisms.

(9) "Department" means the Department of Public Health and Human Services.

(10) "Disinfectant" means a substance or solution, registered with the United States Environmental Protection Agency (EPA), that kills or inactivates viruses and pathogenic microorganisms, but not necessarily their spores.

(11) "Ear lobe piercing" means the puncturing of the ear lobe, but not the ear cartilage, to create a permanent hole for cosmetic purposes.

(12) "Equipment" means all machinery, including fixtures, containers, vessels, instruments, tools, devices, implements, furniture, display and storage areas, sinks, and all other apparatus and appurtenances used in connection with the operation of an establishment.

(13) "Infectious waste" means the definition found in 75-10-1003, MCA.

(14) "Ink cup" means a small container for an individual portion of pigment which may be installed in a holder or palette, and in which a small amount of pigment is placed.

(15) "Instrument" means hand piece, needle, and any other tool that may come in contact with a client's body or be exposed to blood or body fluids during a tattooing or body piercing procedure.

(16) "Jewelry" means any ornament designed for insertion into a pierced area of a client.

(17) "Mobile establishment" means a facility where tattooing or body piercing or both is conducted, utilizing a wheeled vehicle for movement from place to place.

(18) "Operator" means any owner of an establishment or any person who is responsible for the establishment as well as the other artists working at the establishment, for the purpose of meeting the requirements of this chapter.

(19) "Permanent cosmetics", also known as permanent makeup or micropigmentation, means tattooing any part of the face for cosmetic purposes.

(20) "Physician" means a person licensed to practice medicine in Montana by the Montana Board of Medical Examiners under the Department of Labor and Industry.

(21) "Sanitization" means the effective treatment of surfaces of inanimate objects by a product registered by the EPA that provides a sufficient concentration of chemicals and enough time to reduce the bacterial count, including pathogens, to a safe level.

(22) "Sharps" means the definition found in 75-10-1003, MCA.

(23) "Single-use" means items that are intended to be used once then

discarded.

(24) "Sterilize" means to treat an object or surface with a procedure that kills or irreversibly inactivates all microorganisms, including bacteria, viruses, and pathogenic fungi, including their spores.

(25) "Tattoo establishment" means any room, space, shop, or salon, including a temporary or mobile facility, where tattooing is practiced.

(26) "Tattooist" means a person who engages in the practice of tattooing as defined in 50-48-102, MCA.

(27) "Temporary establishment" means a facility where either tattooing or body piercing or both are conducted for not more than 14 days at one location in a calendar year.

(28) "Universal precautions" means the current set of guidelines and controls published by the U.S. Centers for Disease Control and Prevention that includes specific recommendations for the use of protective equipment such as gloves, masks, or protective eye wear whenever contact with blood or body fluids containing blood is anticipated.

(29) "Work room" means a designated room or area in which either tattooing or body piercing takes place.

AUTH: 50-48-103, MCA

IMP: 50-48-102, 50-48-103, MCA

RULE III GENERAL FACILITY REQUIREMENTS (1) Work rooms, restrooms, handwashing facilities, waiting areas, and all establishment areas to which clients have access must be kept clean and free of garbage, litter, unnecessary articles, dust, dirt, and sources of airborne dust or fumes.

(2) Utility rooms, storage rooms, and all other auxiliary rooms separated from other areas of the establishment by closed doors must be in good repair and cleaned as often as necessary to prevent insect or rodent harborage, airborne dust, airborne hazardous chemicals, or other contaminants.

(3) All rooms in the establishment must be provided with an artificial light source equivalent to 20 foot-candles of light three feet off the floor, except as required for work rooms in [Rule VII(5)].

(4) An establishment may not be operated in any room or area used as living or sleeping quarters. An establishment must be separated from any living or sleeping quarters by solid self-closing doors.

AUTH: 50-48-103, MCA

IMP: 50-48-103, MCA

RULE IV WATER SUPPLY (1) An adequate and potable supply of water must be provided.

(2) Before a license may be issued, an establishment using an individual, shared, or multiple user water supply must submit the following to the department or its designee:

(a) satisfactory coliform bacteria and nitrate test results as specified in ARM 37, chapter 38, subchapter 2; and

(b) the results of an onsite sanitary survey of the water supply system to detect sanitary deficiencies.

(3) A supplier of an individual, shared, or multiple user water supply shall conduct a coliform bacteria test of the system at least twice a year with one sample collected between April 1 through June 30 and the second sample collected between August 1 through October 31, and shall conduct a nitrate test of the system at least once every three years. Water tests must be analyzed at a certified laboratory. A supplier shall keep sampling result records for at least three years.

(4) A public water supply system must be constructed and operated in accordance to current applicable laws as regulated by the Montana Department of Environmental Quality.

(5) Nonpotable water sources must be marked "not for human consumption".

(6) Plumbing must be installed and maintained in a manner to prevent cross connections between the potable water supply and any nonpotable or questionable water supply or any source of pollution through which the potable water supply might become contaminated. The potable water system must be installed to preclude the possibility of backflow. A hose may not be attached to a faucet unless a backflow prevention device is installed.

(7) A water supply system is determined to have failed and requires treatment, replacement, repair, or disinfection, when the water supply becomes unsafe, when it exceeds the maximum contaminant levels specified in ARM Title 17, chapter 38, subchapter 2, or inadequate when it is found to be less than 20 psi measured at the extremity of the distribution line during the instantaneous peak usage.

(8) Extension, alteration, repair, or replacement of a water supply system or development of a new water supply system must be in accordance with all applicable state and local laws.

(9) Bottled and packaged potable water must be obtained from a licensed and approved source and shall be handled and stored in a way that protects it from contamination.

AUTH: 50-48-103, MCA

IMP: 50-48-103, MCA

RULE V SEWAGE SYSTEM AND SOLID WASTE (1) An adequate and safe wastewater system must be provided for conveying, treating, and disposing of all sewage. Immediate measures must be taken to alleviate health and sanitation hazards caused by wastewater at the establishment when they occur.

(2) All sewage, including liquid waste, must be disposed of by a public sewage system approved by the Montana Department of Environmental Quality or by a sewage treatment and disposal system constructed and operated in accordance to applicable state and local laws. Nonwater-carried sewage disposal facilities are prohibited, except as permitted by [Rule VIII] for temporary or mobile establishments.

(3) A wastewater system has failed and requires replacement or repair if any of the following conditions occur:

(a) the system fails to accept, treat, or dispose of wastewater as designed;

(b) effluent from the wastewater system contaminates a potable water supply or state waters; or

(c) the wastewater system is subjected to mechanical failure, including electrical outage, or collapse or breakage of a septic tank, lead line, or drainfield line.

(4) Extension, alteration, replacement, or repair of any wastewater system must be done in accordance with all applicable state and local laws.

(5) Mop water or soiled cleaning water may not be disposed of in any sink other than a mop or utility sink or a toilet.

(6) Solid waste must be collected, stored, and disposed of in a manner that does not create a sanitary nuisance and meets the requirements of [Rule XIV] for disposal of infectious waste. Solid waste must be removed from the premises at least weekly to a licensed solid waste disposal facility.

AUTH: 50-48-103, MCA

IMP: 50-48-103, MCA

RULE VI TOILETS AND HANDWASHING FACILITIES (1) Each establishment must have a toilet and handwashing facility conveniently available to clients and artists during all hours of operation.

(2) The toilet room must be located within 200 feet by a normal pedestrian route of the work room and not more than one floor-to-floor flight of stairs.

(3) The toilet room must be vented to the outside, well lighted, and equipped with a self-closing door, toilet tissue, and waste receptacle.

(4) Floors, walls, and ceilings of the toilet room must be in good repair and in clean condition.

(5) Equipment and supplies used for either tattooing or body piercing or both must not be stored or used within the toilet room.

(6) The handwashing facility must be located either within the toilet room or within ten feet of the toilet room door.

(7) The handwashing sink must be provided with hot and cold running water by means of a mixing valve or combination faucet, except as provided in [Rule VIII(2)] for temporary or mobile establishments.

(8) Any self-dispensing, slow-closing, or metering faucet used must be designed to provide a flow of water for at least 20 seconds without the need to reactivate the faucet.

(9) Steam mixing valves are prohibited.

(10) Soap must be conveniently located to the hand sink.

(11) Single-use towels must be conveniently located for drying hands and a waste receptacle provided.

AUTH: 50-48-103, MCA

IMP: 50-48-103, MCA

RULE VII WORK ROOM REQUIREMENTS (1) All tattooing and body piercing procedures must take place in the work room only.

(2) The work room must be separated by a barrier from the waiting area. The room does not need to have complete physical separation, but it must be

segregated by counters, self-closing doors, or other barriers so that clients or other employees may not enter the work room unless they open the barrier to gain access.

(3) The work room may not be used as a corridor for access to other rooms.

(4) Animals are not allowed in the work room, except for patrol dogs accompanying security or police officers and service animals such as guide dogs.

(5) The work room must have a minimum of 50 foot-candles of light measured at the level where the procedure is implemented. Spot lighting may be used to achieve this degree of illumination.

(6) The work room must have adequate ventilation. If heating ducts, vents, or air conditioners discharge into the work room, the intakes for such venting must be filtered, and the filters must be maintained to minimize airborne dust and insects.

(7) Openings to the outside must be protected by such means as self-closing doors, screened or closed windows, or air currents to protect against the entrance of insects, rodents, or other animals. Screening material must not be less than 16 mesh to the inch.

(8) The work rooms must have a handwashing facility unless there is handwashing facility outside the work room within ten feet of the work room door.

(a) If the handwashing facility is outside the work room, the work room door must be a two-way self-closing door.

(b) If controls for wrist or foot activation are not available, single service towels must be used for turning controls off after washing hands.

(c) The handwashing sink must be sanitized at least once each day while the establishment is in operation.

(d) The handwashing sink must be provided with hot and cold running water by means of a mixing valve or combination faucet, except as provided in [Rule VIII(2)] regarding temporary or mobile establishments.

(e) Any self-dispensing, slow-closing, or metering faucet used must be designed to provide a flow of water for at least 20 seconds without the need to reactivate the faucet.

(f) Steam mixing valves are prohibited.

(g) Soap must be conveniently located near the handwashing sink.

(h) Single-use towels must be conveniently located for drying hands.

(9) The work room must have a sufficient number of waste receptacles for the disposal of waste materials.

(a) Waste receptacles must be covered except while in use to prevent contamination of hands and gloves.

(b) Waste receptacles in the work room must be emptied daily.

(c) A dedicated container for the disposal of sharps and a dedicated container for other contaminated waste must be located in the work room in accordance with [Rule XIV] for disposal of infectious material.

(10) The work room must be maintained in a clean condition.

(11) The floor of the work room must be constructed of smooth and impervious materials and must be wet-mopped daily.

(12) Tobacco use, eating, or drinking is prohibited in the work room, except eating and drinking is allowed when needed for first aid purposes.

AUTH: 50-48-103, MCA

IMP: 50-48-103, MCA

RULE VIII TEMPORARY OR MOBILE ESTABLISHMENT (1) A temporary or mobile establishment may be operated if:

(a) the operator submits to the department or its designee a written plan that demonstrates how the temporary or mobile establishment will meet the provisions of these rules, or will use alternatives that provide equivalent protection as provided by these rules; and

(b) the department or its designee issues written approval of the plan.

(2) A temporary or mobile establishment that cannot provide mechanically heated water may provide temperate water for hand washing as long as the water is provided in a system that is constructed and operated in accordance with applicable state and local laws for potable water.

(3) A temporary or mobile establishment that cannot meet [Rule V(1)] regarding sewage systems may use an acceptable portable toilet unit with final waste disposal that complies with applicable state and local laws.

AUTH: 50-48-103, MCA

IMP: 50-48-103, MCA

RULE IX EQUIPMENT AND SUPPLIES (1) Equipment, tools, and jewelry must be clean, in sound condition, and free of rust. Sharp instruments and tools must not be dull. Defective needles may not be used.

(2) Single-use or disposal items must be used only once.

(3) Gloves that come into contact with a client must be single-use nonlatex examination gloves designed for medical or clinical use.

(4) A durable tray must be maintained in the work room for the placement of used articles which require cleaning and autoclaving.

(5) Single-use needles must be disposed of in a sharps disposal container that meets the requirements in [Rule XIV].

(6) Work tables, counter tops, and client contact surfaces must be:

(a) constructed of material that is easily cleanable, smooth, nonabsorbent, and corrosion-resistant; and

(b) cleaned and sanitized with a disinfectant between clients.

(7) The operator must maintain at all times enough sterile supplies, disinfectant, antiseptic, and gloves for three working days.

(8) Disinfectants, cleaning compounds, pesticides, and other chemicals must be stored in such a manner that prevents contamination of equipment, supplies, and work surfaces. Chemical containers must be clearly labeled with the common name of the material. Chemicals must be used in a manner consistent with the manufacturer's labeling.

(9) Instruments, supplies, and other materials that come into contact with the client must be stored in closed clean containers or clean cabinets.

(10) Tables, trays, and equipment may not be shared among artists serving different clients at the same time.

AUTH: 50-48-103, MCA

IMP: 50-48-103, MCA

RULE X BLOOD-BORNE PATHOGEN EXPOSURE CONTROL (1) An establishment operator employing at least one artist shall meet the applicable requirements of 29 CFR 1910.1030, which provides standards for blood-borne pathogen exposure control as promulgated by the U.S. Department of Labor, Occupational Safety and Health Administration. The department hereby adopts and incorporates by reference 29 CFR 1910.1030. Copies of 29 CFR 1910.1030 may be obtained by contacting the Montana Department of Public Health and Human Services, Food and Consumer Safety Section, 1400 Broadway, P.O. Box 202951, Helena, MT 59620-2951.

AUTH: 50-48-103, MCA

IMP: 50-48-103, MCA

RULE XI STERILIZATION OF EQUIPMENT AND JEWELRY (1) All nondisposable instruments used for tattooing or body piercing that can come into contact with blood or body fluids must be individually wrapped and sterilized by an autoclave. All disposable instruments that come into contact with blood or body fluids must come from the supplier individually wrapped and sterile.

(2) All jewelry must be sterilized by at least one of the following methods:

(a) individually wrapped and autoclaved;

(b) come from the supplier individually wrapped and sterile; or

(c) be sterilized with a liquid chemical sterilant that has been approved for use by the U.S. Food and Drug Administration.

(3) Whenever an autoclave is used, the following requirements apply:

(a) Autoclave packaging and a testing indicator for verifying temperatures must be used each time.

(b) The autoclave must be allowed to run a complete cycle for 20 minutes at 15 pounds of pressure at a temperature of 250°F (121°C), or in accordance with the autoclave manufacturer's instructions.

(c) After autoclaving, the package must be dated and initialed by the artist. If the autoclaved instrument or jewelry is not used within six months of the sterilization date, or if the packaging is no longer intact, the article must be rewrapped and resterilized before use.

(d) Monthly biological monitoring must be conducted on the autoclave using standard spore units that are analyzed by a certified laboratory.

(e) Following sterilization, equipment, and jewelry must remain in the autoclave packaging.

(4) Sterile packages must be opened in full view of the client.

(5) Jewelry that is sterilized by a chemical sterilant must be immediately inserted into the client to prevent possible contamination.

AUTH: 50-48-103, MCA

IMP: 50-48-103, MCA

RULE XII CLEANING AND ULTRASONIC USE (1) All nondisposable

instruments used for tattooing and body piercing procedures must be cleaned thoroughly with an appropriate soap or detergent and rinsed completely with potable water.

(2) Each establishment must have at least a one-compartment sink with hot and cold running water for the cleaning of instruments. The sink must be of an adequate size to submerge the instruments being cleaned, except as provided in (3) of this rule.

(3) Establishments that use ultrasonic units with heating elements to clean their instruments are not required to have hot water at the cleaning sink, provided the heating elements can heat the cleaning solution and maintain the temperature according to the manufacturer's specifications.

(4) An ultrasonic cleaning unit must be used in accordance with the manufacturer's instructions. An ultrasonic cleaning unit does not satisfy the sterilization requirements in [Rule XI], with or without the addition of chemical sanitizers.

(5) If the artist uses the ultrasonic unit at the work station to rinse instruments, a single-use cup or single-use liner must be placed in the tank prior to use and changed between clients, unless the tank is autoclaved between clients. The used liner must be disposed of in accordance with [Rule XIV] regarding the disposal of contaminated waste.

(6) Cleaning, dusting, or vacuuming is prohibited during times when clients are being tattooed or pierced.

AUTH: 50-48-103, MCA

IMP: 50-48-103, MCA

RULE XIII SKIN PREPARATION, ASEPTIC TECHNIQUE AND AFTECARE

(1) Aftercare instructions appropriate for the tattooing or body piercing procedure that describe effective means of infection prevention must be provided to the client both verbally and in writing before every procedure.

(2) At all times during the tattooing or body piercing procedure, artists shall use sterile instruments as specified in [Rule XI] and aseptic techniques.

(3) Before and after performing the tattooing or body piercing procedure, artists shall thoroughly wash their hands and wrists in warm running water with soap for at least 20 seconds, scrubbing around and under their fingernails, rinsing completely, and drying with a clean single-use towel.

(4) Artists shall wear a clean outer garment. A hair restraint must be worn if necessary to prevent the artist's hair from contact with the client.

(5) If it is necessary to shave the client's skin area to be tattooed or pierced, the artist shall use single-use razors. Straight razors and replaceable blade units may not be used. After shaving the client's skin, the artist shall:

(a) wash and scrub the artist's hands as described in (3) of this rule; and

(b) wash and rinse the client's area of skin that was shaved.

(6) If the artist wore gloves to wash or shave the client's skin, the artist shall discard those gloves after completing those tasks. The artist shall then put on a new pair of gloves before continuing the procedure.

(7) Before performing the tattooing or piercing procedure, the skin and

surrounding area where the procedure is to be done must be thoroughly dampened with an antiseptic using a clean single-use cotton ball, gauze, or tissue.

(8) If it is necessary to use a marking device, the marking device must be used only once.

(9) New gloves must be put on before each tattooing and piercing procedure.

(10) If the artist's gloved hands become contaminated during the tattooing or body piercing procedure, then the artist shall rewash hands and reglove before resuming the procedure.

(a) Inadvertent contamination of gloved hands may include touching eyes, nose or mouth, answering the phone, opening a door, or retrieving an item from the floor.

(b) If the artist sustains a needle stick, the artist shall resume the tattooing or body piecing procedure with clean and sterile equipment after rewashing hands and regloving.

(11) In the event of blood flow, all materials used to stop the flow of blood or to absorb blood must be sterile and single-use.

(12) Upon completion of the tattooing or piercing procedure, artists shall apply an antiseptic solution to the procedure area with a clean single-use cotton ball, gauze, or tissue.

AUTH: 50-48-103, MCA

IMP: 50-48-103, MCA

RULE XIV HANDLING AND DISPOSAL OF INFECTIOUS MATERIAL

(1) Waste that may have been contaminated with blood or body fluids must be separated from other waste in different containers with biohazard warning labels.

(2) An adequate supply of sharps containers must be maintained on the premises. A sharps container must:

(a) be leakproof, rigid, and strong enough to protect the handler and others from accidental cuts or puncture wounds; and

(b) be closed or capped securely to prevent the loss of contents for disposal.

(3) Waste that may have been contaminated with blood or body fluids, other than sharps, must be placed in moisture-proof single-use containers or bags of a strength sufficient to prevent ripping, tearing, or bursting under normal conditions of use. Also, the bags must be:

(a) securely tied to prevent leakage or the expulsion of solid or liquid wastes during storage, handling, and transportation; and

(b) placed in a durable, leakproof container for storage and transportation.

(4) An artist shall use adequate protections, such as a brush, dust pan, or tongs to pick up any broken glassware in the work room. After engaging in such cleaning, the artist shall wash hands and reglove as described in [Rule XIII] before working with a client.

(5) Laundry that may have been contaminated with blood or body fluids must be stored separately in a leakproof and closed container or bag prior to cleaning.

(6) All infectious waste must be treated and disposed of in accordance with Title 75, chapter 10, part 10, MCA.

AUTH: 50-48-103, MCA

IMP: 50-48-103, MCA

RULE XV RECORD KEEPING AND REVIEW (1) Client records, consent forms, autoclave sterilization test results, and any other records required by this chapter must be maintained on the establishment premises for a minimum of three years. The records must be:

(a) available for review and verification by the department or its designee; and

(b) typed or printed in ink.

(2) Each establishment must keep on the premises current copies of the Montana Code Annotated and Administrative Rules governing tattooing and body piercing establishment, and upon request make these available for review to any artist, client, client's parent, or client's legal guardian.

AUTH: 50-48-103, MCA

IMP: 50-48-103, MCA

RULE XVI CLIENT RECORD (1) The operator must maintain a client record for each client. At a minimum, the client record must include:

(a) a copy of the signed consent form required by [Rule XVII];

(b) the name of the artist who performed the tattooing or body piercing procedure;

(c) the address and telephone number of the establishment;

(d) special instructions or information regarding the client's medical or skin conditions which are relevant to the tattooing or body piercing procedure; and

(e) a written physician referral if one is required by [Rule XXV].

AUTH: 50-48-103, MCA

IMP: 50-48-103, MCA

RULE XVII CONSENT FORM (1) The client must sign a consent form before each tattooing or body piercing procedure. If the client is under the age of 18, then the client's parent or legal guardian must sign the consent form before the procedure.

(2) The consent form must contain:

(a) the client's name and address, the date of the procedure, the design of the tattoo, if applicable, the location of the procedure on the client's body, and any other information that the artist may consider appropriate;

(b) a description of potential complications and side-effects, including abscesses, allergies, excessive bleeding (from body piercing), heavy metal poisoning, infection, keloid formation, muscle paralysis, nerve paralysis, scarring, swelling, and tooth fracture (from oral piercing).

(c) symptoms of infection such as fever, swelling, redness, or drainage;

(d) instructions to consult a physician if symptoms of infection or other complications occur;

(e) the permanent nature of either tattoos or specific piercings or both; and

- (f) a statement by the client that the client:
 - (i) has been provided with the preservice information, both in writing and verbally by the artist; and
 - (ii) consents to the tattooing or body piercing procedure.

AUTH: 50-48-103, MCA

IMP: 50-48-103, MCA

RULE XVIII TRAINING (1) Operators and artists shall complete formal training provided by the department or its designee that includes at least general sanitation, first aid, and universal precautions for preventing the transmission of blood-born pathogens.

(2) Operators shall complete formal training within one year prior to obtaining a license from the department, and at least once in each calendar year of license renewal thereafter. Artists shall complete formal training within 60 days of hire, contract, or apprenticeship with an operator, and at least once every calendar year thereafter.

(3) Equivalent formal training that is not provided by the department or its designee may be permitted if the training contains the same subject matter requirements as specified in (1), and the department or its designee has approved the training.

(4) Each formal training course must provide written documentation to trainees indicating successful completion the course.

AUTH: 50-48-103, MCA

IMP: 50-48-103, MCA

RULE XIX LICENSE REQUIREMENT AND DISPLAY (1) No person shall operate an establishment without a license issued by the department. Only a person who complies with the requirements of this chapter shall be entitled to receive or retain such a license. Licenses are not transferable.

(2) A valid license must be posted in every establishment in a conspicuous location.

AUTH: 50-48-103, MCA

IMP: 50-48-103, 50-48-201, MCA

RULE XX LICENSE APPLICATION (1) Any person desiring to operate an establishment shall submit an application for a license on forms provided by the department. The application must include the name and address of the applicant, and the location and type of the proposed establishment.

(2) The applicant of license and all artists working in the proposed establishment shall be at least 18 years of age at the time of application.

(3) Prior to approval of an application for a license, the department or its designee will inspect the proposed establishment to determine compliance with the requirements of this chapter.

(4) The department will issue a license to the applicant if the applicant

demonstrates that the proposed establishment complies with all applicable requirements of this chapter by plan review, inspection, and upon receipt of the license fee.

(5) Obtaining a license from the department does not relieve the applicant from satisfying applicable requirements from other federal, state, or local agencies. These requirements may include, but are not limited to:

- (a) building code permits and inspections;
- (b) fire and life safety inspections; and
- (c) other business licenses.

AUTH: 50-48-103, MCA

IMP: 50-48-103, 50-48-201, MCA

RULE XXI LICENSE FEE AND EXPIRATION (1) The license fee is \$135.

(2) The license will expire annually on December 31 following the date of its issuance.

AUTH: 50-48-103, MCA

IMP: 50-48-103, 50-48,201, MCA

RULE XXII LICENSE DENIAL AND CANCELLATION (1) A notice of license denial or cancellation, as provided for in 50-48-205, MCA, is properly served when it is hand-delivered to the operator of the license or the person in charge, or when it is sent by registered or certified mail to the last known address of the operator.

(2) The hearing process provided in 50-48-205, MCA, concerning license denial or cancellation, must be conducted by the department pursuant to Title 2, chapter 4, part 6, MCA, of the Montana Administrative Procedure Act regarding contested cases, and ARM 37.5.117.

AUTH: 50-48-103, MCA

IMP: 2-4-201, 2-4-631, 50-48-205, MCA

RULE XXIII REVIEW OF PLANS (1) Whenever an initial license is applied for, the license applicant must submit properly prepared plans and specifications to the department or its designee for review and approval before construction, remodeling, or conversion begins.

(2) The plans and specifications must demonstrate how the establishment will meet the requirements of this rule, including the following:

- (a) a layout of work rooms, waiting areas, auxiliary rooms, toilet rooms, handwashing facilities, doorways, stairways, fixed equipment, and facilities;
- (b) specifications for any autoclave that may be used, including manufacturer and model number;
- (c) copies of the client consent form, client record form, and all applicable aftercare instructions; and
- (d) copies of formal training documentation as described in [Rule XVIII].

(3) If the department or its designee disapproves of the plans, the department or its designee will make the deficiencies known to the applicant.

(4) If the facility was previously licensed or certified by the department as a tattooing or body piercing establishment and no structural modification is involved, the department may waive the requirement for the submission of plans.

(5) Changes in the client consent form, client record form, and all applicable aftercare instructions must be submitted to the department or its designee before implementation.

AUTH: 50-48-103, MCA

IMP: 50-48-103, MCA

RULE XXIV INSPECTION (1) The department or its designee, after proper identification, must be permitted to enter any establishment at any reasonable time for the purpose of making inspections to determine compliance with this chapter and must be permitted to examine the records of the establishment pertaining to compliance with this chapter.

(2) The department or its designee shall conduct inspection of establishments at least once per year. Additional inspections of the establishment may be performed as often as necessary for the enforcement of this chapter. The department will charge a follow-up fee for a third or subsequent inspection if a violation of this chapter is not corrected by the end of the second visit to the establishment. The follow-up fee is \$150.

(3) Whenever an inspection of an establishment is made, the department or its designee will document its findings on an inspection form. A copy of the completed inspection report form will be given to the person in charge of the establishment within ten days of the inspection.

(a) Correction of the violations that the department or its designee finds must be accomplished within the period specified on the inspection form.

(b) Failure to comply with any time limits for corrections of critical item violations may result in cessation of establishment operations.

(c) The completed inspection report form is a public document that must be made available for public review or distribution upon payment of reasonable copying costs.

AUTH: 50-48-103, MCA

IMP: 50-48-103, 50-48-206, MCA

RULE XXV RESTRICTIONS AND PROHIBITIONS (1) A tattooing or body piercing procedure may not occur if:

(a) either the artist of the client is under the apparent influence of alcohol or other mind-altering drugs;

(b) the client has not signed the consent form required by [Rule XVII]; or

(c) the client is under the age of 18, without the explicit in-person consent of the client's parent or legal guardian as provided in 45-5-623, MCA.

(2) If the client is under the age of 18, the parent or legal guardian must accompany the client throughout the procedure.

(3) A written physician referral is required before tattooing or body piercing if the client:

- (a) is taking any drug or dietary supplements that may induce bleeding tendencies or reduce clotting;
 - (b) has a medical condition that is known to cause bleeding tendencies or reduce clotting;
 - (c) shows signs of recent intravenous drug use;
 - (d) has a sunburn, a skin disease such as psoriasis or eczema, a skin infection, or lesions such as a mole in the proposed procedure site; or
 - (e) discloses or evidences allergies or contact sensitivity to pigments, soaps, or other substances that may be used in the procedure.
- (4) The artist may delay or require a medical referral before conducting any tattooing or piercing for any person whose physical health, understanding, or judgment may be in question.

AUTH: 50-48-103, MCA

IMP: 50-48-103, MCA

RULE XXVI VARIANCE (1) A licensee may request a variance to waive or modify compliance with the health requirements of this chapter by petitioning the department. An application for a variance must contain:

- (a) a statement of the proposed variance from the chapter's requirements, citing the relevant rule numbers; and
 - (b) a rationale explaining how the potential public health hazards addressed by the relevant rules will be alternatively addressed by the proposal.
- (2) The department may grant a variance by modifying or waiving the requirements of this chapter if, in the opinion of the department, a health hazard will not result from the variance.
- (3) A licensee must continuously demonstrate compliance with the variance or modification granted by the department. The failure to comply to the department-approved variance or modification may be grounds for license revocation.
- (4) The department reserves the right to deny or revoke a variance if, in its judgment, a health risk may occur.

AUTH: 50-48-103, MCA

IMP: 50-48-103, 50-48-204, MCA

RULE XXVII TATTOOING: PATTERN TRANSFER (1) If the method of pattern transfer involves a reusable plastic or acetate stencil, the stencil must be cleaned and sanitized immediately prior to the application.

- (2) An adherent or emollient applied to facilitate a pattern transfer, or to cover a pattern after transfer, must be from a single-use container or must be extracted from a supply container in a manner to prevent contamination of the adherent or emollient supply.

AUTH: 50-48-103, MCA

IMP: 50-48-103, MCA

RULE XXVIII TATTOOING: COLORS, DYES, AND PIGMENTS (1) Each

tattooist shall use colors, dyes, and pigments from reputable suppliers, designed for tattooing, stored in appropriate clean and sterile containers, and labeled with the manufacturer name and lot number.

(2) Pigments mixed or prepared in the tattoo establishment must be prepared and stored in accordance with the manufacturer's instructions.

(3) A tattooist who becomes aware of a client who has experienced an apparent reaction, allergy, or sensitivity to a pigment used in tattooing must report the condition and pigment information to the Department of Public Health and Human Services, Food and Consumer Safety Section, 1400 Broadway, P.O. Box 202951, Helena, Montana 59620-2951 or the local health officer. Adulterated pigments or those containing deleterious substances may be subject to voluntary hold, manufacturer recall, or other action under the Montana Food, Drug and Cosmetic Act, Title 50, Chapter 31, MCA; the Federal Food, Drug and Cosmetic Act; or other federal, state, or local law.

(4) Pigments or dyes may not be used if they are disapproved of or under recall by the United States Food and Drug Administration or the department under the Montana Food, Drug and Cosmetic Act, Title 50, Chapter 31, MCA.

(5) Individual pigment portions and ink cups must be used for one client, then disposed in accordance with [Rule XIV] pertaining to infectious waste.

(6) If additional pigment must be added to an ink cup during the tattooing, the tattooist shall wash hands and reglove, or use a single-use liner to handle the ink storage container.

AUTH: 50-48-103, MCA

IMP: 50-48-103, MCA

RULE XXIX BODY PIERCING: ADDITIONAL REQUIREMENTS AND RESTRICTIONS (1) If the client is under the age of three, the client's parent or legal guardian must be given verbal and written warning of the inherent choking hazard of the jewelry before the body piercing. This warning may be included on the consent form.

(2) For the purposes of this chapter, body piercing does not include the following:

(a) the practice of electrology as defined in ARM Title 37, chapter 31, subchapter 1;

(b) the practice of a physician or licensed medical professional as long as the person does not hold himself or herself out as a body piercer;

(c) the practice of acupuncture; and

(d) other types of body modifications, including but not limited to cutting muscle to make a permanent split such as tongue-splitting, cutting into bone, trepanation (drilling into the skull), dental modification, amputation, implants, saline injection, vacuum pumping, circumcision, castration, penectomy, and subincision or superincision of genitals.

AUTH: 50-48-103, MCA

IMP: 50-48-103, MCA

RULE XXX BODY PIERCING: EAR LOBE PIERCING EXEMPTIONS

(1) Establishments that perform ear lobe piercing only by using a mechanized presterilized ear-piercing system approved by the department or its designee may be exempted from [Rule VI(2)], [Rule VII(2)], [Rule VII(5)], and [Rule VII(8)] as long as:

(a) the work area in which ear lobe piercing takes place is separated enough from the other areas so that no physical contact can be reasonably expected to occur between the general public and the client or artist;

(b) a minimum of 30 foot-candles of light is provided at the level where the ear piercing is being performed. Spot lighting may be used to achieve this degree of illumination; and

(c) the artist and client must have convenient access to handwashing facilities. If the handwashing facility is not within the work room or within ten feet of the work room door, then an alcohol-based hand sanitizer must be used in accordance with the U.S. Centers for Disease Control "Guideline for Hand Hygiene in Health-Care Settings" (Morbidity and Mortality Weekly Reports, 2002, Vol. 51, No. RR-16) immediately before putting on gloves and immediately after removal of the gloves. The department hereby adopts and incorporates the U.S. Centers for Disease Control "Guideline for Hand Hygiene in Health-Care Settings" (Morbidity and Mortality Weekly Reports, 2002, Vol. 51, No. RR-16). Copies of this guideline may be obtained by contacting the Montana Department of Public Health and Human Services, Food and Consumer Safety Section, 1400 Broadway, P.O. Box 202951, Helena, MT 59620-2951.

AUTH: 50-48-103, MCA

IMP: 50-48-103, MCA

3. The rules 37.112.101, 37.112.105, 37.112.106, 37.112.107, 37.112.112, 37.112.113, 37.112.114, 37.112.120, 37.112.122, 37.112.124, 37.112.126, 37.112.128, 37.112.130, 37.112.135, 37.112.136, 37.112.140, 37.112.143, and 37.112.146 as proposed to be repealed are on pages 37-28241 through 37-28363 of the Administrative Rules of Montana.

AUTH: 50-1-202, MCA

IMP: 50-1-202, MCA

4. These proposed rules, promulgated by the passage of Senate Bill 137 during the 2005 State Legislative Session [Title 50, chapter 48, MCA], are necessary to license and regulate tattoo and body piercing operations in order to protect public health and safety.

The practices of tattooing and body piercing present similar health risks to the client and artist. Both procedures are invasive to the client's skin, with the potential of exposure to blood-borne pathogens and infections. The exposure may lead to the contraction of hepatitis and human immunodeficiency virus (HIV). Most of the facility requirements, processes, training, client screening, aftercare, and general sanitation needed to protect clients and artists are identical for both tattooing and piercing

procedures, as seen in these proposed rules.

When devising the rules, the department obtained input from various tattoo and body piercing practitioners in Montana. It took into consideration comments from a written survey issued to known tattooing and body piercing establishments, professional organizations that represent the industry, local and tribal boards of health and health officers, registered sanitarians, and interested registered nurses. The department reviewed the tattooing rules that exist in Yellowstone County, along with regulations from other states including Florida, Kentucky, Ohio, Oklahoma, and Oregon. The department also received input from a work group consisting of the state medical officer, epidemiologist, registered nurses, registered sanitarians, and legal counsel. Finally, the department consulted with tattooists and body piercers at their places of work to see if the proposed rules would be practical in their implementation.

Instead of amending the existing tattoo rules found in ARM Title 37, chapter 112, subsection 1, the department chose to repeal those rules and draft new ones since the standards are the same in many instances for both tattooing and body piercing. The department retained much of the requirements of the existing tattoo rules, as specified more fully below.

Rule I Purpose: The rule explains the differentiation between establishments licensed and regulated by the department, and those licensed and regulated by the local health authorities. Unlike other establishments the department licenses and regulates, Title 50, chapter 48, MCA, allows either the department or the local health authority to have exclusive jurisdiction over tattooing and body piercing establishments. Rule I is necessary to clarify to the public that the rules pertain only to those establishments licensed and regulated by the department.

Rule II Definitions: Rule II ensures that words or phrases used in the ensuing rules are clearly defined so those reading the rules will attribute the same meaning to each word or phrase. This rule is necessary so that the ensuing rules are understandable.

Rule III General Facility Requirements: The department proposes to repeal ARM 37.112.105 and replace it with Rules III, IV, and V. Rule III contains the same requirements in ARM 37.112.105, except the new rule applies to both tattoo and body piercing establishments. Rule III establishes standards for the whole structure of the establishment except for the work room where tattooing and body piercing take place and for which requires more rigorous standards. The standards in Rule III are reasonably necessary to minimize sources of filth, bacteria, and viruses that could be transported from an establishment's common areas to the work room.

Rule IV Water Supply: Water can become contaminated with disease-causing microorganisms or hazardous chemicals. Because of these hazards, Rule IV requires water to come from a source that is protected, tested, stored, transported, and dispensed in a sanitary manner. This rule mostly adopts the requirements in ARM 37.112.105. One change includes having the water supply tested in the spring

and fall for noncommunity water supplies. Spring and fall are the most likely times that groundwater is vulnerable to contamination due to the rising and lowering of the water table. The department considered making no changes from the testing requirements in ARM 37.112.105, but it determined that testing at random times of the year is not likely to reveal contamination episodes.

Rule IV adds the requirement that a sufficient volume of potable water must be available to meet the needs of the establishment. Sufficient volume requirements are necessary to maintain adequate cleaning of the facility, equipment, and hands. The term "potable" replaces "sterilized water or bottled, distilled water" found in ARM 37.112.105 because other sources or processes can deliver water fit for consumption and hygiene. The proposed requirements in Rule IV are current standards for other establishments licensed by the department.

Rule V Sewage System and Solid Waste: Proper treatment of human waste protects ground water supplies, surface waters, and land that is accessible to people or pets. It also prevents the attraction of rodents and insects that can be vectors of disease.

Rule V reiterates the same requirements in ARM 37.112.105(1)(c) for sewage systems. However, it adds requirements for temporary and mobile establishments to collect and dispose of sewage in a sanitary and lawful manner. The department considered not allowing an exception for temporary or mobile establishments, however these operations pose little if any health risks as long as they use an approved onsite sewage system or a community sewage system.

Rule V adds that solid waste must be removed at least weekly to a licensed disposal facility. This requirement is needed because sanitary solid waste collection, storage, and final disposal prevent conditions that may attract rodents and insects harboring diseases that can spread to humans. The department considered not adding the requirement, but the weekly removal of solid waste is a minimum sanitation standard for other licensed establishments and residential properties. It also does not create an unreasonable burden to tattooing and body piercing establishments.

Rule VI Toilets and Handwashing Facilities: This rule retains the requirements in ARM 37.112.105(1)(d), and adds that toilets and handwashing facilities must be conveniently located within 200 feet of where tattooing and body piercing takes place, and be no more than one floor-to-floor flight of stairs. These requirements are necessary so no confusion exists as to what constitutes reasonable distances, which may be too subjective. The department considered requiring toilet and handwashing facilities to be located within the establishment. Doing so would be unnecessary for establishments that operate within other business buildings, or temporary or mobile establishments which can provide access to public toilet rooms easily.

Rule VI prohibits the storing of tattooing and body piercing equipment and supplies in the toilet room in order to prevent the risk of contamination or adulteration. The department considered not adding this requirement but determined that the need to

protect equipment and supplies from cross-contamination outweighed an establishment's potential loss of storage space.

The department added the requirement for hot and cold water at handwashing sinks to be mixed so that warm water is provided. When only hot or cold water is available, handwashing compliance may be reduced. Also, a warm water flow of at least 20 seconds is necessary for adequate handwashing to prevent contamination of clients. Steam mixing valves are prohibited because they are difficult to control and may lead to scalding.

Rule VII Work Room Requirements: This rule maintains much of ARM 37.112.106. The requirements in ARM 37.112.106(1), (3), and (5) have been inserted in Rule VII(1) through (4) regarding the need to have a separate room for tattooing and body piercing procedures, having it blocked off from common areas, having it to be inaccessible to people not needed during procedures, and prohibiting animals from the area. Because the work room should be the most sterile place, these requirements are needed to help protect the area from contaminants in order to prevent infections.

Rule VII(5) changes the minimum lighting requirement from 10 foot-candles of light, as found at ARM 37.11.106(2)(a), to 50 foot-candles of light. Adequate lighting is essential for cleanliness, accident prevention, and performing certain functions such as reading labels and discerning the color of substances. Other states such as Florida and Oklahoma have similar illumination requirements. Further, the lighting guideline for general use is 50 to 100 foot-candles of light, as specified in "Environmental Engineering", 5th edition, Salvato, Nemerow, and Agardy, which is a widely used to set sanitation standards.

In devising Rule VII(5), the department considered a lower lighting standard such as having 20 foot-candles of light as a minimum requirement. This lighting standard is adequate for stairways and corridors, but not for work rooms where it is crucial to avoid piercing arteries and being able to differentiate between the colors of dyes. The department also considered requiring 100 foot-candles of light, but found that the minimum of 50 foot-candles of light would be less burdensome on operators and would provide adequate protection for clients.

The department added Rule VII(7) regarding the need for outside protection for outer doors and windows of the work room. This requirement minimizes the potential for disease-bearing insects and rodents entering the areas. An alternative considered was requiring outer protection for the entire establishment, not just the work room, however sterility is most important in the room where tattooing and body piercing takes place. Another alternative considered was to not require outer protection. Since tattooing and body piercing are invasive procedures, outer protection is needed to preserve equipment sterility.

Rule VII(8)(a) through (h) provides handwashing facility requirements that are similar to ARM 37.111.106(2)(c). The department included the requirements in this rule

because hand hygiene is critical at the time of tattooing and body piercing.

Rule VII(9) is the same as that in ARM 37.112.106(2)(d), except the new version requires waste receptacles to be covered except while in use. It is important to cover waste receptacles to keep out flies and other insects that can transmit disease-causing microorganisms. The department considered not implementing this requirement, however covering waste receptacles provides an easy method of protection.

Rule VII(10) and (11) provide the same requirement for keeping the work area clean as provided in ARM 37.112.106(4) and (8). The department expanded the requirements for the cleanliness and sanitation of equipment and supplies in Rule IX, described below.

Rule VIII Temporary or Mobile Establishment: This rule continues to permit temporary or mobile establishments, seen in ARM 37.112.105(3) and (4). Tattooing and body piercing performed at temporary or mobile establishments are subject to the same potential for blood-borne pathogen disease transmission and infection as procedures conducted at permanent establishments.

The department added requirements that are more permissible than the original rule.

Rule VIII(2) allows the use of room temperature water instead of mixing hot and cold water for hand washing as long as the water meets the standard for safe drinking water. Using temperate water for hand washing is important to encourage complete cleaning and rinsing.

Rule VIII(3) allows the use of approved portable toilet units. Compliance with rules promulgated by the Montana Department of Environmental Quality and local regulations ensures that sewage waste disposal from portable toilets is appropriately done.

The department considered not allowing temporary or mobile establishments. This prohibition is unnecessary because these operators are capable of meeting the same health and safety requirements as permanent establishments during the short amount of time they are in operation.

Rule IX Equipment and Supplies: This rule retains the requirements in ARM 37.112.107, except the department expanded the standards to cover body piercers. In Rule IX(1) and (2), the department requires all equipment, tools, and jewelry to be in good condition or be used once. This rule is necessary to ensure the prevention of infection and transmission of blood-borne pathogens.

Rule IX(3) requires disposable gloves to be nonlatex. According to the U.S. Centers for Disease Control, studies show that 8 to 12% of health care workers who are regularly exposed to latex become latex sensitive, as opposed to 1 to 6% of the general population. The symptoms of latex allergies include skin rashes and inflammation, respiratory inflammation, respiratory irritation, and, in rare cases,

shock. The reactions usually begin within minutes of being exposed to latex, or hours later. The department considered recommending the use of nonlatex gloves rather than requiring them. Since latex reactions can lead to serious conditions such as shock and potential death, and since there are alternative products that are easily obtainable, the department decided to require the use of nonlatex gloves.

Rule IX(5) contains the terms "disinfectant" and "antiseptic" rather than the phrases of "germicide cleaner or tincture surgical soap" and "70% isopropyl alcohol" found in ARM 37.112.107(4). The new terms provide operators with options in choosing from a variety of products that are equally effective. An alternative to using the general terms "disinfectant" and "antiseptic" included listing all known products approved for such uses. Making a list of products could restrict the use of new products that would be just as effective.

Rule IX(5)(d) and (e) require enough sterile supplies, disinfectant, and antiseptic to be available on the premises based on the number of clients served. These requirements are more general than those found in ARM 27.112.107(4) with its specific requirements for 18 sets of needles, 300 disposable gloves, etc. The department chose to ease the standards because the volume of customers can vary greatly, and the department recognizes that requiring certain numbers of supplies can result in unnecessary expenses for establishments serving only a limited number of clients. The department has found that the operator is best suited to determine anticipated needs during busy periods or special events.

Rule X Blood-Borne Pathogen Exposure Control: This rule replaces the requirements in ARM 37.112.112, which contained some but not all of the standards promulgated by the federal Occupational Safety and Health Administration (OSHA). Rule X adopts and incorporates by reference the OSHA standards for blood-borne pathogen exposure control found in 29 CFR (Code of Federal Regulations) 1910.1030. The OSHA standards provide requirements for universal precautions to prevent contact with blood or other potentially infectious materials, work practice controls, personal protective equipment, housekeeping, containing and disposing contaminated sharps, waste containment, laundry, Hepatitis B vaccinations, post-exposure evaluation and follow-up, communicating hazards to employees, information and training, and recordkeeping.

The department considered not adopting 29 CFR 1910.1030, or only adopting some of the standards. The department rejected these alternatives because compliance with all OSHA standards pertaining to blood-borne pathogen exposure control is critical to protect public health.

Rule XI Sterilization of Equipment and Jewelry: This rule maintains the requirements in ARM 37.112.113. Added is the requirement for instruments and jewelry to be sterile when they may come in contact with blood or other bodily fluids. This addition is necessary because clean instruments and jewelry do not provide the same level of protection as sterile ones.

Rule XI adds the requirement that jewelry which has been chemically sterilized must be immediately inserted into the client's piercing. This requirement ensures that jewelry does not become contaminated from its handling or placement on a nonsterile work surface.

Rule XI further requires autoclaved packages that are no longer intact to be rewrapped and resterilized. The contents of an autoclaved package will only remain safe as long as the packaging is intact.

The department eliminated the allowance for dry heat sterilization found in ARM 37.112.113(2). The provision was effective for one year after the adoption of the original tattooing rules, which was April 17, 1998. The department chose not to allow dry heat sterilization because it is not conducive to being monitored for its effectiveness in sterilization. Autoclave sterilization is more effective because each process can be monitored using color change tape indicators, and the overall effectiveness can be monitored through the use of spore units.

In devising the requirements of Rule XI, the department did not consider any alternatives because the procedures can be easily implemented. Sterile instruments and jewelry assure the prevention of infection and the spread of blood-borne pathogen diseases. The requirement for changing gloves between clients, listed in ARM 37.112.113(1)(f), was moved to Rule XIII, which provides requirements for skin preparation, aseptic technique, and aftercare.

Rule XII Cleaning and Ultrasonic Use: This rule contains five changes to the requirements in ARM 37.112.114. First, Rule XII requires all reused instruments to be cleaned and rinsed. This requirement is needed to assure the removal of blood, body fluids, and other contaminants before the instruments are used for another client.

Second, Rule XII requires establishments to have at least a one-compartment sink of adequate size with hot and cold running water. This requirement is needed because the use of warm water and complete submersion are more effective in cleaning than using cold water or swabbing.

Third, Rule XII allows establishments with ultrasonic units to waive the hot water requirement for cleaning sinks. Ultrasonic units use heat, and they provide an effective cleaning method as long as there is a one-compartment sink providing water for rinsing.

Fourth, Rule XII requires ultrasonic units to be used in accordance with the manufacturer's instructions at all times, not just for cleaning needles, tubes, or other parts of equipment specified in ARM 37.112.114. The department determined that there may be other uses for the ultrasonic unit that are not contemplated by the rule. The proper use of an ultrasonic unit is needed for adequate cleaning.

Finally, Rule XII prohibits cleaning, dusting, or vacuuming during times of performing

tattooing or body piercing. This requirement is the same specified in ARM 37.112.124. The department felt that the requirement was better suited in Rule XII rather than in a rule about the tattooing or body piercing procedure.

Rule XIII Skin Preparation, Aseptic Technique, and Aftercare: This rule intends to replace ARM 37.112.120 regarding skin preparation of tattooing, some of the requirements in 37.112.124 regarding tattoo application, and 37.112.126 regarding aftercare. The regulations for skin preparation, aseptic technique, and aftercare were placed in one rule because these topics all relate to both tattooing and body piercing processes.

Rule XIII(1) requires aftercare instructions to be provided to the client before the tattooing or body piercing procedure takes place. This provision is necessary because a client needs to be aware of the care and maintenance before agreeing to the procedure. Also, because some piercings require the assistance of another person for aftercare, the client needs to know this information beforehand. An alternative to Rule XIII(1) is to not provide aftercare instructions before the procedure, but the department believes consumers need to make informed decisions before engaging in any of the invasive procedures.

Rule XIII(2) requires artists to use aseptic techniques and sterile instruments during tattooing and body piercing. The department did not consider alternatives to this requirement because maintaining sterility is crucial to prevent infections and disease transmissions.

Rule XIII(3) requires wrists to be washed as well as the hands. The department considered requiring artists to wash up to the elbows. The department rejected this requirement because it is more appropriate for food service operations where food can possibly come into contact with forearms. Another alternative was not including wrists to be washed, however any contaminants on the wrists may be transferred to the exterior of gloves when they are put on.

Also, Rule XIII(3) requires the drying of wrists and hands with single-use towels. The department considered allowing the use of hot air dryers in the work room, but single-use towels are necessary so they can be used to turn off the sink controls. Also, artists will not be tempted to dry their hands on their potentially-contaminated clothing after using the air drying system.

For Rule XIII(7), the department removed requirements to use specific products for skin disinfection after shaving, as specified in ARM 37.112.120 (2) (b) and (c). Instead, the new rule more appropriately reflects the level of cleaning or disinfecting that is needed. The department considered retaining the requirements in ARM 37.112.120(2)(b) and (c), but found that only cleaning and rinsing after shaving is needed because the skin site is to be disinfected immediately before the tattooing or piercing.

The requirements for the artist to change gloves after shaving the client and before

each new procedure, and the requirement to use single-use sterile products to stop blood flow, have been moved from ARM 37.112.122 and 37.112.124. Those provisions have been reworded in Rule XIII(6), (9), and (11) to be applicable to both tattooing and body piercing. The department did not consider any substantive changes because the requirements are effective methods of preventing disease and infection.

Rule XIII(10) requires the artist to change gloves if they become contaminated, as specified in ARM 37.112.124(2)(d). The department did not consider any alternatives to this provision because contaminated gloves place the client at risk for contracting a disease or infection.

Some requirements of ARM 37.112.120 have been removed. Nailbrushes no longer must be used by only one person. Sharing bars of soap and nailbrushes do not spread disease because it is the action of the washing and rinsing that removes bacteria and viruses.

Also, as seen in Rule XIII(3), hot water is no longer required for washing hands. Warm or temperate water is as effective in removing filth and disease-causing microorganisms.

Rule XIII(4) does not require hair restraints at all times, but only when hair has the potential to come into contact with the client. The department does not find it necessary for every artist to wear hair restraints regardless of whether a risk of contact exists.

Rule XIII does not require the use of antibacterial ointment and covering after tattooing, as specified in ARM 37.112.126(1), because of conflicting recommendations as to what constitutes appropriate aftercare. Some experts in the tattooing industry report that antibacterial ointment can result in allergic reactions and that only a lubricating ointment is needed. Some believe it is necessary to cover tattoos to prevent infections, while others assert that air drying is needed for best results. The aftercare protocol may change with the development of new information, technologies, and products. Aftercare instructions may vary based on the size and type of procedures, as well as the individual client's skin reaction to the procedure. A suggestion has been made that the department develop the aftercare instructions. The department finds that, other than restricting the use of recalled products or harmful substances, developing aftercare instructions is beyond the scope of the department's expertise. The department therefore chose to leave the aftercare instructions up to the individual artist's assessment.

Rule XIV Handling and Disposal of Infectious Material: This rule is substantively the same as ARM 37.112.130. The department removed the provision defining "sharps" because the term is defined in Rule I. The term "infectious waste" was removed because it is redundant with the term "contaminated article".

The department removed the provision in ARM 37.112.130 on having persons

trained in infection control to remove all waste receptacles. This requirement is not always necessary when waste receptacles do not contain contaminated materials.

Finally, Rule XIV was formatted to comply with the Montana Secretary of State's rule structure requirements. The department considered not making these changes, however eliminating redundant terms and streamlining the format provides for better readability.

Rule XV Record Keeping and Review: This provision sums up all record keeping and review requirements in one rule. In many areas of the existing tattooing rules, the record keeping requirements are scattered in various provisions. For instance, ARM 37.112.113 requires autoclave sterilization records to be kept on the premises, but it does not specify a time limit. ARM 37.122.135 requires client records to be kept for at least two years. ARM 37.112.136 does not specify any record keeping standards for client consent forms. Under Rule XV, all records must be kept on the premises for three years and be available for review by the regulatory authority. The department considered putting the record retention period in the various rules pertaining to the particular records, but concluded that a separate rule will facilitate compliance and reduce confusion for operators. The department considered allowing some records to be kept off the premises for mobile or temporary establishments, but decided Rule VIII provides enough flexibility to deal with this issue.

Rule XV(1)(b) requires the records to be in ink or typed. The department considered not having this requirement, but found that using permanent transcription methods ensures the integrity of the records.

Rule XV(2) requires copies of the state's statutes and administrative rules governing tattooing and body piercing be on the premises and available to any artist, client, or client's parent or guardian. This requirement allows for easier referral, which will facilitate compliance. Also, clients have a right to know the requirements for their own protection. Artists may want copies handy to demonstrate to clients how the regulations restrict their practices. The department considered not requiring on-premise copies of the statutes and rules, but concluded that access to the law is necessary and outweighs any inconvenience to operators.

Rule XVI Client Record: This rule substantively remains the same as ARM 37.112.135. The provisions were changed to accommodate body piercing, comply with the provisions of Title 50, chapter 48, MCA, and conform to rule formatting guidelines from the Secretary of State. The department placed an additional requirement that the client's medical or skin conditions must be included only if they are relevant to the procedure. The department considered not adding the requirement but concluded it would relieve the operator's burden of keeping all medical information revealed to them if the information does not pertain to tattooing or body piercing. It further facilitates the client's right to privacy regarding medical information.

Rule XVII Consent Form: This rule replaces ARM 37.112.136. Rule XVII requires the client consent form to be signed before tattooing or piercing, and be signed by a parent or guardian if the client is under the age of 18. This provision is consistent with 45-5-623, MCA, which states that tattooing or body piercing a minor without parental or guardian consent is a criminal offense.

Rule XVII also contains the requirement that instructions be given on consulting a physician if the client notices any signs of infection. The instructions help ensure that the client seeks medical help first rather than returning to the operator. The department did not consider an alternative to this requirement because time may be a critical factor in preventing an infection from entering the blood stream where it has the potential to affect the heart or other organs.

Rule XVIII Training: This rule requires operators and artists to complete training for general sanitation, first aid, and universal precautions for preventing the transmission of blood-borne pathogens. Uniform training assures that licensed operators have knowledge and are capable of assisting when medical emergencies may occur. This rule is necessary because tattooing and body piercing are invasive procedures that can lead to fainting, excessive bleeding, infection, and blood-borne disease such as hepatitis and HIV.

The department considered adding training and certification requirements for cardiopulmonary resuscitation (CPR), however tattooing and body piercing clients are no more likely to suffer an event requiring CPR than other members of the general public. The clients are more at risk for excessive bleeding or fainting.

The department also considered the suggestion of having minimum competency standards for all artists similar to that of occupational licensing. The standards concerning techniques, experience, or artistic ability are not health-related. Providing such standards would be beyond the scope of the legislative mandate on rulemaking provided in 50-48-103, MCA.

Rule XVIII(2) requires training to be completed annually and before an applicant can obtain a license. The department considered allowing the issuance of licenses before the completion of training, but rejected the idea because understanding universal precautions is critical to prevent disease transmission. Training is therefore needed before operating any establishment.

The department decided to have the training be completed annually so as to reinforce important information and provide updates on any practices. Yearly training on universal precautions is consistent with OSHA recommendations. The department considered training every two or three years but rejected the proposal because of the importance of knowing the universal precautions to protect public health.

Also in Rule XVIII(2), any training that has been completed longer than one year before a complete precensing plan submittal will not count towards the training

requirements. The department considered allowing previous training that occurred with the past five years before the initial license application, but rejected the proposal because any information learned may be deemed outdated or the potential licensee may have forgotten many important concepts.

Rule XVIII(2) further requires other artists to complete their training within 60 days of their employment, contract, or apprenticeship. Sixty days allow time for the new artist to work with the operator before investing any time or finances towards training. The department considered having new artists complete training before they are able to work, but determined it was not necessary since the individuals will be working under the supervision of the operator until all training is completed.

Rule XVIII(3) allows training to be obtained from sources other than the department if it finds the course material to be equivalent and approves the training. The rule requires the submission of written documentation showing the completion of the training. Allowing training offered by other organizations provides flexibility for operators and artists. The department considered mandating all training to come from it, but found that other organizations provide equivalent training opportunities which may be more advantageous for the trainee.

Rule XIX License Requirement and Display: This rule reinforces the requirement in 50-48-201, MCA, that persons operating a tattoo or body piercing establishment obtain a license from the department. Additionally, the rule requires the licenses to be conspicuously displayed at the establishment so that the regulatory authorities and the public can be assured of current licensing. Licensing indicates that the establishment has met the department's minimum public health requirements.

Rule XX License Application: Rule XX(2) requires applicants and artists to be at least 18 years of age. The department considered requiring only the operator to be of the age of majority, however every artist engaging in tattooing or body piercing risks exposure to blood-borne pathogens which could result in life threatening illnesses such as hepatitis and HIV. Also, tattooing and body piercing procedures are invasive procedures that place clients at risk. Maturity is necessary for understanding the serious consequences of noncompliance with the health and safety requirements.

Rule XX(3), (4), and (5) assures that license applicants and their proposed establishments are in compliance with all health and safety laws before the department issues the licenses. The rule allows the department to obtain minimum information about an establishment, and to permit the inspection of the premises to assure that all health and safety requirements are met before a license is issued. It further put the applicants on notice that they must also comply with any other federal, state or local laws. The department did not consider any alternatives to these rule provisions because licensing and compliance with regulations are tied together to assure public health and safety.

Rule XXI License Fee and Expiration: Section 50-48-103(4), MCA, permits the

department to devise rules that "impose fees for licensure, inspection, enforcement, training, and administration. " Rule XXI sets the license fee at \$135 per year. The department estimated that this amount paid by each establishment will cover the department's costs for rule development, publication, mailing, and travel, and the expenses for including tattooing and body piercing in its licensing database, for the first year that the licensing program is in operation. The department projects that in subsequent years, its costs will not be associated with rule development but will involve travel expenses and personnel time for inspection and enforcement activities. The department considered a reduced license fee for multi-type establishments offering both tattooing and body piercing, however it found that the costs for the department are not significantly reduced. Also, 50-48-201 (3), MCA, requires separate licenses for each type of establishment.

The department estimates that 85 licenses will be issued per year at \$135 each, and anticipates 100 participants for training through the department at \$60 each, for a total yearly revenue of \$17,475. The expenses for the first year of implementing the licensing program, including database development to track the licenses, rule development, initial training, publication of the rules, mailing of the rules, and travel, are anticipated to be \$17,475. The net impact to the state's general fund is expected to be \$0.

Rule XXI(2) lists the annual license expiration date on December 31 of each year. This date is used as the expiration date of other annual licenses issued by the department's Food and Consumer Safety Section. An alternative expiration date considered was June 30, the date ending the department's fiscal year. Using this date, however, would not allow the department to track the licenses with its existing data system. Further, devising a new data system with a different expiration date will lead to higher license fees given that the department's costs would increase.

Rule XXII License Denial and Cancellation: This rule is necessary to provide a proper procedure for giving notice and conducting fair hearings for license denial or cancellation. This rule is equivalent to the requirements for other establishments licensed by the department. Rule XXII is needed to comply with the requirements of the Montana Administrative Procedure Act, found in Title 2, chapter 4, MCA, and the department's standard hearing procedures found in ARM Title 37, chapter 5.

Rule XXIII Review of Plans: Rule XXIII requires a license applicant to submit plans, including the layout of the facility, autoclave specifications, copies of the forms required by these rules, and training documentation. This rule allows the department to provide its input so that the license applicant is complying with all laws and regulations before the start of any construction, remodeling or conversion of an existing structure into a tattooing or body piercing establishment. The department considered issuing licenses based on inspections only without any plan review, however doing so would not assure that the facilities will initially meet all requirements. Having to comply after the fact can lead to unforeseen expenses that can be quite costly for licensees.

Rule XXIV Inspection: This rule requires the department to inspect each establishment at least yearly. Routine inspections are necessary to detect practices and conditions that may be hazardous to the establishment's clients. In order to carry out an effective inspection, the department must be able to have reasonable access to the establishment. An alternative to the requirements in Rule XXIV would be to only have inspections in response to complaints from the public or before the opening of the establishment. Doing so would be inadequate because conditions and practices that affect public health can change over time. Yearly inspections also provide opportunities for the department to answer any questions or educate operators on current matters of public health and safety.

Rule XXIV(2) states the department will impose a fee of \$150 for a third or a subsequent follow-up inspection if a violation found during the first inspection is not remedied by the second visit. Setting this fee in rule is authorized by 50-48-103(4), MCA, which permits the department to set fees for "licensure, inspection, enforcement, training, and administration."

The follow-up inspection fee is similar to that allowed for retail food service establishments. Section 50-50-205(3), MCA, provides that a county or other local government may not impose an inspection fee or any additional fee beyond that for the license except when a violation of any requirement persists and is not corrected after two visits to the establishment.

Similarly with tattooing and body piercing establishments, a repeat violation should be corrected promptly to protect the public's health. Any follow-up visits to assure that the operator has complied results in more than time and expenses for the department. The fee of \$150 for subsequent inspections will help alleviate the department's costs. The department also hopes that the fee will provide an incentive to operators to correct any violations as soon as possible.

The \$150 fee will not result in any windfall for the department or the state. The average hourly salary, including any benefits, for a registered sanitarian working for the department is \$17. The daily salary for an eight hour day would be \$136.00. This cost to the state does not include transportation and travel expenses. For instance, rental of a vehicle from the state's motor pool is \$9.40 per day, plus \$0.048 per mile traveled. Rather than stating in the rule that a third or subsequent follow-up inspection will result in the operator paying for the inspector's hours, plus all expenses incurred for travel, if any, the department chose to set a certain fee.

Rule XXV Restrictions and Prohibitions: This rule contains the same restrictions and prohibitions found in the existing tattoo rule, ARM 37.112.140. Rule XXV(3) adds the requirement for a physician referral if a client is taking any herbs or has a medical condition that is known to cause bleeding tendencies. This provision is necessary because herbs and medical conditions can cause bleeding tendencies as well as certain medications.

The provisions in ARM 37.112.140 pertaining to sunburns, rashes, wounds, and

puncture marks were changed because these conditions are not considered skin diseases or infections. A physician referral is required if a tattooing or piercing will involve penetrating a mole because it could lead to complications such as excessive bleeding or, in rare circumstances, the spread of cancerous cells. As an alternative, the department considered listing all known conditions that would prevent tattooing or body piercing, but it determined that the general categories of sunburns, skin diseases, infections, and lesions would be sufficient. Medical expertise must be left to health care professionals if there are any questions.

Rule XXVI Variance: This rule allows establishments to apply for variances from the rules' requirements as long as the operators prove that public health hazards are adequately controlled. The department considered not allowing for a variance process, however variances allow both the operator and the department to account for the changes in technology and advances in procedures that provide the same effectiveness as the specified requirements in these rules.

Rule XXVII Tattooing: Pattern Transfer This rule closely follows the existing requirements in ARM 37.112.122. The department eliminated the listing of specific products for cleaning and sanitizing, specific items to be contained in closed cabinets, specific items which must be single-use, and specific storage containers and handling procedures to prevent the contamination of the transfer adherent. There are multiple products on the market that are effective for cleaning and sanitizing. Single-use items can be kept clean and sterile in several ways, not just by storing them in closed cabinets. Additionally, adherent can be transferred and stored in many ways to prevent its contamination. The department considered leaving the requirements in ARM 37.112.122 unchanged, however the proposed changes allow for adequate cleaning, sanitizing, storage, and handling of supplies while allowing the artist to choose methods and products that work best for the individual. The glove requirements in ARM 37.112.122(4) were transferred to Rule XIII so that they apply to both tattooing and body piercing.

Rule XXVIII Tattooing: Colors, Dyes and Pigments The requirements of ARM 37.112.128 and 37.112.124(2) were combined in this rule. The department has made three additions to the existing requirements. Color, dyes, and pigments must be designed for tattooing, stored in clean and sterile containers, and be labeled with the manufacturer's name and lot number. The U.S. Food and Drug Administration (FDA), which regulates food, drugs, and cosmetics, relies on complaints to restrict products from use. Tracing ink back to the supplier is vital for responding to public health problems caused by contaminated products or harmful formulations.

The department considered keeping the current language in ARM 37.112.128(1), which only requires that inks come from "reputable suppliers". The department found that option to be inadequate for the practice of tattooing today since many of the pigments used in tattoo inks are not approved for skin contact. Some inks are industrial grade colors that are suitable for printing ink or automobile paint. Also, new formulations of ink are placed on the market without any testing to see if they are safe. Another option considered by the department was listing all ingredients

available, however having such a list may not be suitable for the operator because manufacturers are not required by law to list their ingredients on labels.

Rule XXIX Body Piercing: Additional Requirements and Restrictions Rule XXIX (1) requires operators to provide both verbal and written warnings to parents or guardians of children under three years of age who are undergoing piercings about the choking hazards of jewelry. The department considered not having this requirement, however it found that children less than three years old have the highest risk for death and injury from mechanical airway obstruction. This condition is due to their immature anatomy, their developmental stage, and their natural tendency to put objects in their mouths. Children who choke run the risk of death, permanent brain damage due to the lack of oxygen, or other complications caused by airway blockage. Earrings are not permanent fixtures, so there is a risk of them falling out accidentally. They are of the size that can be easily swallowed.

Section 50-48-102, (1) MCA, defines "body piercing" as the penetration of skin to make a hole, mark, or scar that is generally permanent in nature. There are many forms of body modification that may be misconstrued as body piercing. The statute did not contemplate tongue splitting, implantations, dental modifications, amputations, or forms of cosmetic surgery. Although these practices are rare in Montana currently, they may become more common if they gain in popularity. Rule XXIX (2) is therefore needed to classify the practices that are not included in the statutory definition of body piercing. Doing so protects the public's health and safety.

Rule XXX Body Piercing: Ear Lobe Piercing Exemptions This rule exempts licensees from complying with Rules VI(2) and VII(2), (5), and (8) as long as the establishment is restricted to ear lobe piercing with a presterilized ear piercing system. Ear lobe piercing involves only the piercing of the ear lobe and not the ear cartilage, as defined in Rule I.

The approval of the mechanized gun is necessary so that sterility can be verified and products can be recalled by the federal Consumer Product Safety Commission or other federal regulatory agencies. A separate work room is not required as long as the work area is separated to the extent that no physical contact can be reasonably expected to occur between the general public and the client or artist.

Handwashing facilities do not have to be located in the work area if adequate facilities are conveniently available and alcohol-based hand sanitizers are used in accordance with the CDC's guidelines. The department chose to adopt and incorporate by reference the CDC's "Guideline for Hand Hygiene in Health-Care Settings" (Morbidity and Mortality Weekly Reports, 2002, Vol. 51, No. RR-16) because it provides the most current scientific information on hand cleanliness and the effective use of alcohol-based hand sanitizers. The guidelines contain information on what ingredients the hand sanitizers should contain, and how the hand sanitizers should be used in conjunction with regular handwashing and the use of disposable gloves.

The department recognizes that piercing ear lobes carries the same inherent risks of blood-borne pathogen exposure as other types of piercings. However, there is a reduced potential for infection due to the anatomy of the ear lobe. Infections from upper ear cartilage piercing can be especially serious. Because cartilage does not have its own blood supply, taking antibiotics to combat any infections in the area are ineffective since the drug cannot travel through the blood stream to the infection site. The infections can lead to cartilage damage and serious, permanent ear deformity. Most complications reported in ear piercing have been located in the cartilage areas, not the ear lobes. Also, ear lobe piercing establishments tend to use a presterilized system that involves no handling of the jewelry or other parts of the piercing instrument that contacts the client. As a result, the department has determined that the requirements for ear lobe piercing establishments may be less restrictive, but that the sanitization requirements for equipment and jewelry sterility, hand hygiene, and training on blood-borne pathogen control continue to be necessary to protect public health.

5. Interested persons may submit their data, views, or arguments either orally or in writing at the hearing. Written data, views, or arguments may also be submitted to Gwen Knight, Office of Legal Affairs, Department of Public Health and Human Services, P.O. Box 202951, Helena, MT 59620-2951, no later than 5:00 p.m. on November 2, 2006. Data, views, or arguments may also be submitted by facsimile (406) 444-1970 or by electronic mail via the Internet to dphhslegal@mt.gov. The department also maintains lists of persons interested in receiving notice of administrative rule changes. These lists are compiled according to subjects or programs of interest. For placement on the mailing list, please write the person at the address above.

6. The Office of Legal Affairs, Department of Public Health and Human Services has been designated to preside over and conduct the hearing.

/s/ Michelle Maltese
Rule Reviewer

/s/ Joan Miles
Director, Public Health and
Human Services

Certified to the Secretary of State September 25, 2006.